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Purpose:

The Johns Hopkins Department of Pathology is responsible for providing in vitro diagnostic services through its Pathology and Laboratory Medicine services. Additionally the Department is responsible for the quality of patient care laboratory and pathology services performed by all Johns Hopkins Hospital and Johns Hopkins University clinical laboratories providing information for patient care decision-making. It has oversight responsibility for Point of Care Testing performed by non-laboratory personnel. The Office of CQI Programs within the Department of Pathology performs the task of monitoring QI activities and regulatory compliance of all patient care testing areas

Scope:

1. Sites of provision of laboratory services
 - Johns Hopkins Hospital
 - Johns Hopkins University
 - Johns Hopkins Bayview Hospital. Howard County Hospital
 - Johns Hopkins Outpatient Center
 - Johns Hopkins at Greenspring
 - Johns Hopkins at Whitmarsh
 - Johns Hopkins at Odenton
 - Johns Hopkins Community Physicians
 - Johns Hopkins Outreach Clinics

2. Pathology Laboratory Services
 - Autopsy
 - Clinical Chemistry
 - Cardiac Pathology
 - Cytopathology
 - Flow Cytometry
 - Gastrointestinal Pathology
 - Gynecologic Pathology
 - Head and Neck Pathology
 - Hematology and Coagulation
 - Histology
 - HIV Specialty Services
 - Immunology
 - Immunopathology
 - Liver Pathology
 - Medical Microbiology
 - Molecular Pathology and Cytogenetics
 - Neuropathology
 - Pancreatic Pathology
 - Pediatric Pathology

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- Pulmonary Pathology
- Renal Pathology
- Surgical Pathology Consultation Services
- Transfusion Medicine Urology

Regulatory / Quality Oversight

1. The Department of Pathology is charged with the responsibility to oversee all clinical laboratory services provided within the Johns Hopkins Hospital and Johns Hopkins University School of Medicine. The purpose of this oversight is to ensure that the institution complies with CLIA, CAP, Joint Commission, State of Maryland and all other applicable laboratory regulatory requirements. It is administered by the Johns Hopkins Hospital Department of Pathology Continuous Quality Improvement (CQI) Office. The Johns Hopkins Medical Laboratories (JHML) Certification Program was developed in response to the charge.
2. The Pathology Office of Continuous Quality Improvement Programs (CQI) is responsible for ongoing monitoring of quality improvement and regulatory compliance of all areas that provide laboratory testing for patient care. CQI staff provide oversight and guidance for quality improvement activities and reports of occurrence.
3. A patient care laboratory is defined as an area performing laboratory testing and for the purpose of reporting patient specific results for the diagnosis, prevention or treatment of any disease.

JHML CQI Services

1. On-site Laboratory Reviews
 - a. Mock surveys and assessments
 - b. Utilize CAP checklist questions, CLIA standards and Joint Commission Standards
 - c. Provide continuous survey readiness
 - d. Review personnel requirements (change in directorship or technical staff). Perform HR file audits.
 - e. Issue quality reports to the laboratory director
 - f. Review corrective action plans for non-compliant items
 - g. Communicate accreditation updates/changes
 - h. Issue JHML Certificate (Renewals every 2 years)
2. Ongoing Monitoring of QA and Regulatory Compliance
 - a. Proficiency Testing Coordination
 - Assist with the selection of appropriate PT materials
 - Order PT materials

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- Research alternative PT as necessary
 - Provide consultative review
 - Track corrective action documentation
 - b. Safety Compliance –
 - Coordinate environmental safety rounds with the JH Safety Office (2 times/year)
 - Coordinate report to labs, monitor corrective actions
 - Ensure annual employee safety updates are administered
 - Provide laboratory representation at hospital safety workgroup meetings
 - c. Assist with completion and coordinate submission of license and accreditation applications/renewals (Joint Commission, State/Out of State/, CAP).
 - d. Coordinate accreditation inspections. Review findings with laboratories, discuss and collect corrective action plans, submit plans to accreditation agency. Communicate final report to laboratories.
 - e. Provide assistance in monitoring quality improvement initiatives and outcomes.
 - f. Track all laboratory Reports of Occurrence for identification and resolution of problems
 - g. Provide training/education as needed for laboratory compliance
 - h. Communications – Publish and distribute newsletters to provide regulatory and accreditation updates to laboratories
 - i. Conduct pre-survey and post-survey informational presentations
3. Maintain updated library of regulatory and compliance reference material
 4. Interface/coordinate communications between labs and regulatory agencies
 5. Respond to questions concerning laboratory regulations/operations.
 6. Communicate and disseminate new policies and guidelines in an accurate and timely fashion

Special Services (Additional on-site surveys and/or consultations as needed)

1. Introduction of new tests/procedures – review regulatory and quality assurance compliance prior to implementation. Ensure appropriate proficiency testing/QA procedures are implemented.
2. New equipment – provide consultative input on instrument validations
3. Specialized training/education in response to individual department needs. (Provider Performed Microscopy, Phlebotomy, Quality Systems, etc.)

Reviewed by Laboratory Director
J. Brooks Jackson, MD 9/01/09